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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANTS : Steven Alan Dunham, et al.

EXAMINER : J. Taylor

SERIAL NO : 09/719,867

ART UNIT : 1634

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PAPER NO : 8

FOR : METHODS OF IDENTIFYING AND CHARACTERIZING MUTATIONS  
WITHIN BACTERIAL DNA GYRASE AND FABI

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**RESPONSE TO RESTRICTION REQUIREMENT**

May 22, 2002

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This is a response to the Office Action dated March 19, 2002 having a period for reply of three (3) months.

**Remarks**

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121 and § 372.

- I. Claims 1, 2, 4-24 and 36, drawn to processes for identifying and characterizing mutations.
- II. Claims 3, and 25-30, drawn to proteins and mutations of the GyrA of *Neisseria gonorrhoeae*.
- III. Claims 31-35, drawn to proteins and mutations of the FabI of *N. gonorrhoeae*.

The Examiner has asserted that proposed Groups I, II and III are not so linked as to form a single general inventive concept under PCT Rule 13.1.

PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a **technical relationship** among those inventions involving one or more of the **same or corresponding special technical features**. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.  
(emphasis added)

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In the present invention, all of the designated groups have a technical relationship and share a "special technical feature." Specifically each group is related to a novel method of identifying and characterizing mutants having resistance to antibacterial compounds. Accordingly, examination of all three groups together is appropriate under PCT Rule 13.2.

The Examiner is also requiring further restriction of Groups II and III because they contain "products which contain the recitation of multiple, individual amino acid sequence substitutions." The Examiner asserts that "[t]hese species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept." The Examiner supports this conclusion with the statement that "each group represents a different amino acid substitution which is independent of the others, and may be present one without the other." For Group II the Examiner is requiring the Applicants to choose one of the mutations (Asp 90 to Glu, Ser91 to Cys, Asp95 to His, Glu 161 to Gly, Glu 161 to Lys, Asn65 to His, Asp80 to Gly, and Glu62 to Lys.) described for GyrA and the corresponding strain. For Group III the Examiner is requiring the Applicants to choose one amino acid change in claims 31-35 and identify the corresponding strain from Claim 32.

Applicants respectfully traverse this further restriction of Groups II and III because all the strains or mutants contained within each group involve the same technical features. All the strains and proteins of group II involve mutations in the GyrA protein which confer antibiotic

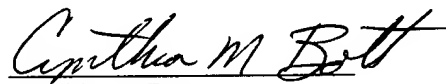
resistance and thus they share the same special technical feature. Likewise, all the strains and proteins of group III involve mutations in the FabI protein which confer antibiotic resistance and thus they share the same special technical feature.

### Conclusion

For the reasons presented above, Applicants urge the Examiner to withdrawal the restriction requirement and examine Groups I-III together, or at the very least, to keep all the species of Groups II together and all the species of Group III together.

The Applicants hereby elect Group I, with traverse, for prosecution on the merits. Because the Examiners requirement for election of a specific mutant is inapplicable to Group I, Applicants have not elected a specific mutant. Applicants hereby withdraw from prosecution the claims directed to Group II and III, without prejudice, and reserve the right to file a Divisional application(s) to the non-elected claims.

Respectfully submitted,



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